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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,772	02/22/2002	Janet K. Yamamoto	UF-267XC1	1105

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EXAMINER

PARK, HANKYEL

ART UNIT PAPER NUMBER

1648

18

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,772

Applicant(s)

YAMAMOTO ET AL.

Examiner

Hankyel T. Park

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-14, 36-39 and 43-46 is/are allowed.
- 6) ☒ Claim(s) 1-5, 15-35 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicants' submission of the amendment and a supplemental IDS filed on July 24, 2003, Paper Nos. 16 and 17, respectively, is acknowledged.
2. The rejection of claims 1-21, 29-39 and 41-46 under 35 U.S.C. 103(a) are withdrawn in view of the amendment of the claims to recite "a non-feline animal."
3. However, the rejection of claims 22-28 and 40 under 35 U.S.C. 103(a) is maintained because the claims were not amended to recite "a non-feline animal."

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 15-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inducing an immune response to a FIV or HIV, does not reasonably provide enablement for a method for treating or preventing FIV or HIV infection in a human or a non-feline animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants have shown in cats FIV antigens induce antibodies to FIV that cross-react to HIV-1; however, the applicants have not shown such HIV antigens would indeed prevent FIV or HIV infection in a human or a non-feline animal. It is well known in the

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art that no such preventive method is proven for a human subject. Applicants have not shown convincing data to prove the contrary to that knowledge.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Johnston et al. (R1 of supplemental IDS submitted on July 28, 2003).

Johnston et al. teaches a method for inducing an immune response to a FIV in a non-feline animal, i.e. a macaques. Johnston et al. discloses detection of FIV specific sequences in PBMC (Fig. 2) and anti-FIV antibodies in sera (Fig. 3) from infected macaques.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5, 15-18 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (R1 of supplemental IDS submitted on July 28, 2003).

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Johnston et al. teaches a method for inducing an immune response to a FIV in a non-feline animal, i.e. a macaques. Johnston et al. discloses detection of FIV specific sequences in PBMC (Fig. 2) and anti-FIV antibodies in sera (Fig. 3) from infected macaques.

Given the fact that FIV can infect a non-feline animal, it would be *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to try to immunize a non-feline animal susceptible to FIV infection against FIV. The one of ordinary skill would be motivated to use synthetic FIV peptide, natural or recombinant FIV protein or a fragment thereof, or polynucleotide comprising a sequence that encodes an FIV protein as immunogen against FIV, because such practice is well known in the field of immunology, lacking any evidence to the contrary.

10. Claims 6-14, 36-39 and 43-46 are deemed to distinguish over the prior art.
11. Claims 1-5, 15-35 and 40-42 are not allowed.
12. Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hankyel T. Park, Ph.D., whose telephone number is (703) 305-

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7255. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Wednesdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Hankyel T. Park, Ph.D.

December 13, 2003



HANKYEL T. PARK, PH.D
PRIMARY EXAMINER